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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,853	10/12/2001	Michael J. Amdahl	6741.US.01	9852

23492 7590 10/24/2006

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EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,853	AMDAHL, MICHAEL J.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' submission filed on 7/27/2006 is acknowledged.

Claims 1-11 and 15 are pending.

Claims 12-14 and 16 are cancelled.

Claims 1-11 and 15 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5-6 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Answer to arguments

Claims 5 and 9-11 were rejected in the previous office actions mailed 8/4/2003 and 4/10/2006 because the limitation "bPTH/80" was indefinite. Applicants argue that the limitation "the initial dose is about the 'bPTH/80'" clearly means that the initial dose is the baseline PTH divided by a factor of 80. Applicants cite a number of paragraphs from the specification that allegedly support the applicants' argument. The specification discloses on page 4 that an initial dose is equal to the bPTH divided by a denominator based upon the outcome of a regression model. The specification does not disclose that "80" is the outcome of a regression model and

that "bPTH/80" is the "bPTH" divided by a factor of 80. The limitation "bPTH/80" may mean, for example, the initial dose of vitamin D equals the amount of bPTH divided by factor of 80; the initial dose equals the amount of some other PTH (called PTH/80); the initial dose equals a dose (or an initial dose) of the dose of vitamin D for the hormone bPTH/80; the initial dose is determined from a graph and is the dose corresponding to the PTH equal PTH/80 or PTH divided by 80; or some other initial dose, as set forth in the previous office actions. In addition, the specification and the prior art disclose that a dose of a vitamin D is measured in mcg/kg of dry weight of a person (see pages 2, 8, and 9 of the specification), while the PTH is measured in pg/ml of serum (page 6 of the specification). If PTH measured in pg/ml, for example, 800 pg/ml, is divided by a factor of 80, then according to applicants an initial dose of the vitamin D is 100 pg/ml, which does not make sense because the dose is measured in mcg/kg of dry weight and the interrelation of the PTH measured in pg/ml and a dose measured in mcg/kg of dry weight of an individual is not clear. Thus, the examiner maintains that the limitation "the initial dose is about the bPTH/80" is unclear, and therefore also maintains the rejection.

Claim 6 was rejected in the office action mailed 4/10/2006 because it was not clear what "final dose" recited in line 8 (step c) was intended. Applicants did not amend the claim and did not specifically argue with respect to the rejection. The examiner maintains that the limitation is still not clear for the reasons set forth in the previous office action, and therefore the rejection is also maintained.

Claim Rejections - 35 USC § 102

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin, *Am. J. Kidney Diseases*, 32(4), Suppl. 2 (October 1998), pages S61-66.

Claims 10 and 11 were rejected in the previous office action over Martin. Applicants argue that Martin does not disclose that an initial dose of vitamin D is about the bPTH/80.

In response to the argument, it is noted that Martin discloses a baseline PTH being 800 pg/ml (fig. 2), which is divisible by 80, and therefore Martin discloses "bPTH/80". Marin further discloses an initial dose of vitamin D (S62), which is administered when the bPTH is about 800 pg/ml. Therefore, Martin discloses an initial dose of vitamin D is about the bPTH/80.

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Knutson, US 5,602,116.

Claims 10 and 11 were rejected in the previous office action over Knutson. Applicants argue that Knutson does not disclose that an initial dose of vitamin D is about the bPTH/80.

In response to the argument, it is noted that Knutson discloses a baseline PTH being 400 and 480 pg/ml, which is divisible by 80 (col. 11, line 9). Knutson also discloses an initial dose of vitamin D, which is administered when the bPTH/80 is, for example, 400 or 480 pg/ml (Example 3). Thus, Knutson discloses the limitation "an initial dose of vitamin D is about the bPTH/80."

Claim Rejections - 35 USC § 103

Claim 1-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin, *Am. J. Kidney Diseases*, 32(4), Suppl. 2 (October 1998), pages S61-66, as applied to claims 10-11 above, in view of Riviere, US 6,066,091, and further in view of SAS Technical Support, GRAPH/GPLOT, 1990.

The claims were rejected in the previous office action over Martin, Riviere, and SAS. Applicants argue that Martin does not disclose that an initial dose of vitamin D is about the bPTH/80. Applicants also argue that neither Riviere nor SAS disclose a linear regression analysis used by the instant inventors to determine an initial dose of a compound.

In response to the argument, it is noted that Martine discloses the limitation "an initial dose of vitamin D is about the bPTH/80," as set forth above. It is further noted that only claim 2 recites "a zero intercept linear model." Claims 1, 3-9, and 15 recite "a regression analysis." Riviere does disclose a regression analysis for extrapolating pharmacological data (col. 2) and extrapolating a withdrawal interval for an adjusted dose of a compound from a prior withdrawal interval for a corresponding prior dose (col. 2; col. 8-9; col. 10, lines 36-40; claims 1, 3, 7). Thus, Riviere discloses using a regression analysis for determining an initial dose of a compound.

With regard to the argument about a linear regression analysis, it is noted that claim 2 recites "a zero intercept linear model." Riviere discloses using "a slope of the line" analysis for extrapolating a dose (col. 2, lines 22-34; col. 10, lines 36-40; claims 1, 3; fig. 2, 4, 6E) and "a slope" and "an intercept deflecting concentration (col. 8, lines 50-67). Riviere also discloses determining a concentration at time zero (col. 2-3) and fig. 2 defining intercepts and slope-parameters (col. 9, lines 10-19 and col. 10, lines 36-49). Thus, Riviere does disclose a regression analysis and specifically, a zero intercept linear model.

For the reasons stated above and in the previous office action, the examiner maintains that Martin, Riviere, and SAS disclose "an initial dose of vitamin D is about the bPTH/80," "a regression analysis," and " zero intercept linear model," and therefore the rejection is also maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-6, M-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marina Miller
Examiner
Art Unit 1631

MM

MARJORIE A. MORAN
PRIMARY EXAMINER
10/10/06